



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/841,580

04/24/2001

Andrea Califano

YOR920000687US2

5406

7590

04/20/2005

Ryan, Mason & Lewis, LLP  
Suite 205  
1300 Post Road  
Fairfield, CT 06430

EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/841,580	<b>Applicant(s)</b> CALIFANO ET AL.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 17-19, 23-25 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 23-25 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*for*

Art Unit: 1631

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' arguments, filed 23 March 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3, 17-19, 23-25, and 29 are currently pending.

#### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 17-19, 23-25, and 29 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the reasons set forth in the previous Office Action.

Applicant argues the following in regard to the utility rejection:

1) Applicant argues that "all pending claims recite, in part, deriving a transformation that transforms a plurality of gene expression signals into transformed gene expression signals for a gene resulting in a uniform distribution of the transformed gene expression signals. The uniform

Art Unit: 1631

distribution of the transformed gene expression signals may be used to determine gene expression patterns". Applicant cites MPEP 2107 section II, parts (A) (3) and (B) (1).

This is not persuasive. The Examiner maintains that there is no recited utility for a uniform distribution of data from random gene expression signals of unknown origin, as recited in the instant claims. It is acknowledged that the specification provides utility for the transformation of gene expression signals from controls (healthy individuals) and transformation of gene expression signals from a phenotype set (unhealthy individuals) that are then both used for comparison of expression levels between the two sets (page 6 of specification). However, the instant claims do not recite such steps of transformation of healthy and unhealthy gene expression signals that are then compared to assess differences or similarities in the expression levels. There is no immediate benefit provided for the transformation of a single set of gene expression signals of unknown origin. And therefore, the instant claims lack utility.

2) Applicant argues that "beginning on page 18, line 23, it is described that statistically significant patterns found in the phenotype set can be used to build a discriminant function. The discriminant function can then be used to determine whether or not a sample belongs to the phenotype or control set". This is not persuasive. As stated above, the instant claims are drawn only to a single transformation of a set of undistinguished gene expression signals. There is neither recitation of a statistically significant pattern found in a phenotype set, nor comparison to determine membership in a phenotype or a control set. For these reasons, the claims lack utility.

Claims 1-3, 17-19, 23-25, and 29 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial, credible or a

Art Unit: 1631

well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons set forth in the previous Office Action.

3) Applicant points the Examiner to page 7, line 18 and page 13, line 3 to provide support for deriving a transformation and using it to transform a plurality of gene expression signals into transformed gene expression signals resulting in a uniform distribution of the transformed gene expression signals. The transformation is defined at page 13. Applicant argues that one would know how to make and use the invention. This is not persuasive. Normalization of a random set of gene expression signals without the comparison outlined in the specification and above, does not teach one of skill in the art how to use the said invention. How does one make a comparison with just one set of random transformed expression signals? The claims remain rejected under 112, 1<sup>st</sup> paragraph.

**Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 17-19, 23-25, and 29 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office Action.

Applicant argues the following:

Art Unit: 1631

1) Applicant argues that the “Examiner alleged, e.g., on page 4, 1<sup>st</sup> paragraph or the Office Action, that in order to practice the claimed invention one of ordinary skill in the art must be able to transform data that transforms gene expression signals, which constitutes undue experimentation”. Applicant points out that “a transformation, e.g., transformation  $f_g$  (equation (1)), shown on page 13, line 16, of the specification, can be used to convert entries in a phenotype matrix. The argument is moot in view of Applicant amendment.

2) The Examiner maintains that one of skill in the art would not have known how to use the invention as recited in the instant claims. Without a recitation of a comparison step using two different sets of gene expression signals from different sample or tissues, etc. one of skill in the art would not have known how to use the instant invention and therefore, the claims lack enablement.

### **Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 17-19, 23-25, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “deriving a transformation that transforms the plurality of gene expression signals into transformed gene expression signals for the gene, resulting in a uniform distribution of the transformed gene expression signals within a selected interval...” It remains unclear whether or not this step is intended to transform a gene expression signal into a uniform

Art Unit: 1631

distribution so that the uniform distribution is used to somehow detect gene expression patterns.

The Examiner contends that this series of steps is circular in nature. Clarification is requested through clearer claim language.

No claims are allowed.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 15, 2005

Lori A. Clow, Ph.D.

Art Unit 1631

*Lori A. Clow*

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*

4/18/05